

REPORT

SUPREME COURT ESTABLISHES A NEW STANDARD
OF REVIEW FOR CLAIM CONSTRUCTION

February 3, 2015

On January 20, in a 7-2 decision, the Supreme Court issued a decision in *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.* overturning the Federal Circuit's practice of reviewing all aspects of claim construction on appeal *de novo*. In summary, the Supreme Court held that, although the ultimate construction of a claim is still to be reviewed *de novo*, if there is an underlying subsidiary factual dispute about a claim term (e.g., if there is a dispute about extrinsic evidence presented during the claim construction process), the district court's findings of fact must be reviewed under the more deferential "clear error" standard.

I. BACKGROUND**A. Relevant Case Law**

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996) (*Markman*), the Supreme Court held that the ultimate question of proper claim construction is a legal issue to be decided by a judge, not a jury. Although the Supreme Court in *Markman* was silent as to whether an appellate court should defer to a trial court on claim construction, the Federal Circuit, in the *Cybor* case,¹ relied on the Supreme Court's decision in *Markman* to hold that claim construction should be reviewed *de novo* on

¹ *Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448 (Fed. Cir. 1998) (*en banc*).

appeal. In a separate recent decision, the Federal Circuit, sitting *en banc*, reaffirmed its practice of *de novo* review of claim construction rulings.²

B. Lower Court Proceedings

Teva owns a patent directed to a method of manufacturing Copaxone, a drug used to treat multiple sclerosis. The active ingredient of Copaxone is a polymer and the relevant claim recites that the "molecular weight of [the polymer] is 5 to 9 kilodaltons."

Teva sued Sandoz for infringement, and Sandoz alleged that Teva's patent was invalid as indefinite under 35 U.S.C. § 112(b). In this regard, Sandoz alleged that the term "molecular weight" could refer to (1) the peak average molecular weight, (2) number average molecular weight, or (3) weight average molecular weight. Sandoz alleged that because Teva's specification and claims failed to provide a definition for the term "molecular weight," and failed to describe how the molecular weight was calculated, the term "molecular weight" was indefinite.

After hearing competing expert testimony provided by both parties, the District Court

² *Lighting Ballast Control, LLC v. Philips Electronics North America Corp.*, 744 F.3d 1272 (Fed. Cir. 2014) (*en banc*). For more details of the decision, please see our March 14, 2014 Special Report, "Sharply Divided *En Banc* Federal Circuit Reaffirms Application of a *De Novo* Standard of Review for Claim Construction."

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determined that one of ordinary skill in the art would have understood "molecular weight," as used in the patent claims, to refer to the peak average molecular weight of the polymer. In making this determination, the District Court relied on Teva's expert's interpretation of Figure 1 of the patent specification (a graph showing how the molecular weights of three different samples were distributed). Teva's expert testified that one of ordinary skill in the art would have interpreted Figure 1 of the patent specification as referring to the peak average molecular weight because of the method used to create Figure 1 (size exclusion chromatography). In view of this testimony, the District Court determined that Teva's claims were sufficiently definite, and that Teva's patent claims were infringed.

On appeal, the Federal Circuit reviewed the District Court's claim construction *de novo*, and reversed the District Court's decision. Among other things, the Federal Circuit noted that Teva's expert agreed with Sandoz's arguments that the number average molecular weight and weight average molecular weight could also be calculated from Figure 1. The Federal Circuit also noted that the peaks shown in Figure 1 do not correspond to the numbers reported in the figure legend, and that the numbers reported in the figure legend are closer to the weight average molecular weight than to the peak average molecular weight. Thus, the Federal Circuit disagreed with the District Court's conclusion that one of ordinary skill in the art would have understood "molecular weight" in the patent claims to mean "peak average molecular weight." Rather, the Federal Circuit concluded that the meaning of "molecular weight" as used in the patent claims is unclear and indefinite. Thus, the Federal Circuit held that the patent claims are invalid under 35 U.S.C. §112(b).

II. SUPREME COURT DECISION

A. Majority Opinion

The question presented to the Supreme Court was what standard of review should be applied on appeal when claim construction involves an underlying subsidiary factual dispute about a claim term (which the Supreme Court characterized as claim construction with "evidentiary underpinnings," a phrase from the *Markman* decision).

The majority began its analysis by reviewing Federal Rule of Civil Procedure 52(a)(6). This rule states that a court of appeal must not set aside a district court's findings of fact unless it is "clearly erroneous." In reviewing the rule, the majority confirmed that it applies to both subsidiary and ultimate factual findings, and found no exceptions in the application of the rule with respect to claim construction involving "evidentiary underpinnings." Therefore, the majority held that Rule 52(a)(6) itself does not create an exception for claim construction.

Next, the majority discussed its opinion in *Markman*. The majority found that *Markman* "neither created, nor argued for, an exception to Rule 52(a)." The decision in *Markman* held that the ultimate question of proper claim construction is an issue of law for the judge, and therefore, as later determined by the Federal Circuit, the ultimate legal question of proper claim construction should be reviewed *de novo* on appeal. But, according to the majority, *Markman* did not create an exception to Rule 52(a)(6) regarding review of any subsidiary underlying facts found by a district court in construing a patent claim. Indeed, as noted above, the decision in *Markman* recognized that claim construction is a practice with "evidentiary underpinnings," and that subsidiary fact-finding is sometimes necessary. *Markman* thus also does not create an exception to Rule 52(a)(6).

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The *Markman* decision analogized construing the claims of a patent to construing the terms of other written instruments, such as contracts and deeds. The Teva majority noted that when a dispute arises as to the meaning of a term in a contract, extrinsic evidence may be used to establish the meaning of the disputed term, and this subsidiary fact finding must be reviewed for clear error (not *de novo*). The majority indicated that in such circumstances, a clear error review is particularly important in patent cases where the district court must become familiar with the particular technology at issue: "[a] district court judge who has presided over, and listened to, the entirety of a proceeding has a comparatively greater opportunity to gain that familiarity than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred."

B. Application of the Clear Error Review

The majority also provided a detailed explanation, with examples, to follow when applying clear error review to subsidiary fact-finding in claim construction. In summary, the majority explained that when a district court only reviews evidence intrinsic to the patent (the specification, claims, and prosecution history), the district court's claim construction amounts solely to a determination of law, and thus must be reviewed *de novo* on appeal. However, where the district court looks beyond the intrinsic evidence and consults extrinsic evidence to construe a claim (e.g., to understand the technology or the meaning of a term in the art at the relevant time), the district court may need to make subsidiary findings of fact that bear on the ultimate construction of a given term. This subsidiary fact-finding must be reviewed for clear error on appeal. The district court, after deciding the factual dispute, will then interpret the claim in light of the factual findings, and this ultimate

claim construction is reviewed *de novo* on appeal. According to the majority:

For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term *in the context of the specific patent claim under review*.

The majority recognized that in some cases, the findings of fact may be dispositive of the ultimate legal question of the proper meaning of a claim term. The majority noted that even in these cases, the findings of fact must be reviewed for clear error. "Simply because a factual finding may be nearly dispositive [of the ultimate legal question of claim construction] does not render the subsidiary question a legal one."

C. Dissenting Opinion

The dissent agreed that there is no special exception in Rule 52(a)(6) for claim construction. However, the dissent argued that the district court made no findings of fact within the meaning of the rule.

In support of its argument, the dissent compared the interpretation of a patent claim to the interpretation of a statute and a land patent (a grant of land from the government to an individual). When interpreting a statute or land patent, no findings of fact within the meaning of the rule are made. Therefore, the dissent concluded that all aspects of claim construction should be reviewed *de novo*, even when a district court has to look beyond the intrinsic evidence to construe a claim. The majority disagreed, noting, among other things, that (i) the dissent's position

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runs contrary to the recognition in *Markman* that claim construction has "evidentiary underpinnings," and (ii) the Court "has never previously compared patent claim construction in any here relevant way to statutory construction."

III. RECOMMENDATIONS

The Teva decision underscores the importance of ensuring that claims are clear and well drafted during prosecution. This can be done by avoiding claiming unique terms, terms used in an unconventional manner, and terms unique to a particular technical field. If these terms must be used in the claims, they should be clearly defined and consistently used in the specification. In addition, the case highlights the importance of sufficiently defining claimed properties in the specification, including describing the method by which properties recited in the claim are determined. This can be of particular importance when a property is measured differently depending on various industry standards (e.g., ANSI, JIS, ASTM, etc.).

When considering the strength of an opinion on patent infringement or validity, careful consideration should be given to the extent that extrinsic evidence is relied upon in support of a favorable claim construction analysis. Under the standard articulated in the Teva decision, reliance on extrinsic evidence may give rise to subsidiary factual findings by a district court that could not be disturbed by the Federal Circuit absent a finding of clear error.

Similarly, the new clear error standard must also be considered when formulating a claim construction strategy in litigation. Depending on the client's claim construction positions, heightened reliance on expert declarations and testimony during the claim construction process should be considered to ensure that a clear record is developed for the district court to thoroughly consider in construing

claims, which could also be important on appeal for the Federal Circuit to evaluate whether there is clear error. In this regard, relevant facts that could be subject to a clear error review may include the level of ordinary skill in the art, the meaning of a particular claim term in ordinary use or as used in a particular field, the interpretation of a patent's disclosure by a person of ordinary skill in the art, the normal practices or standards used by a person of ordinary skill in the art, etc.

Although the Teva decision does not specifically address the standard of review for claim construction decisions on appeal from the Patent Trial and Appeal Board (PTAB), presumably, similar deference would be given to underlying factual determinations made by the PTAB regarding claim construction.

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Oloff PLC is a full-service Intellectual Property law firm based in historic Alexandria, Virginia. The firm specializes in patent, copyright, trademark, and antitrust law and litigation, and represents a large and diverse group of domestic and international clients, including businesses ranging from large multinational corporations to small privately owned companies, major universities, and individual entrepreneurs.

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